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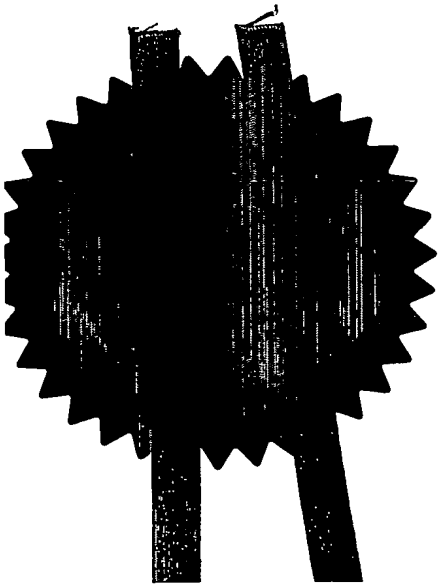

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Request for grant of a patent

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12SEP03 E836764-1 D00027
P01/7700 0.00-0321327.9

1. Your reference — 38.81749/001

2. Patent application number *(The Patent Office will fill in this part)* — 0321327.9

11 SEP 2003

3. Full name, address and postcode of the or of each applicant *(underline all surnames)*

Veryan Medical Ltd
Old Peacock Cottage
Vann Lane
Chiddingfold
GU8 4XU
England

Patents ADP number *(if you know it)* 8717275001

If the applicant is a corporate body, give country/state of incorporation — England

4. Title of the invention — Tubing

5. Name of your agent *(if you have one)* — Frank B. Dehn & Co.

"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*

179 Queen Victoria Street
London
EC4V 4EL

Patents ADP number *(if you know it)* — 166001 ✓

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Country	Priority application number *(if you know it)*	Date of filing *(day / month / year)*

7. If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application

Number of earlier application	Date of filing *(day / month / year)*

8. Is a statement of inventorship and of right to grant of a patent required in support of this request? *(Answer 'Yes' if:*

a) any applicant named in part 3 is not an inventor, or
b) there is an inventor who is not named as an applicant, or
c) any named applicant is a corporate body.
See note (d))

Yes

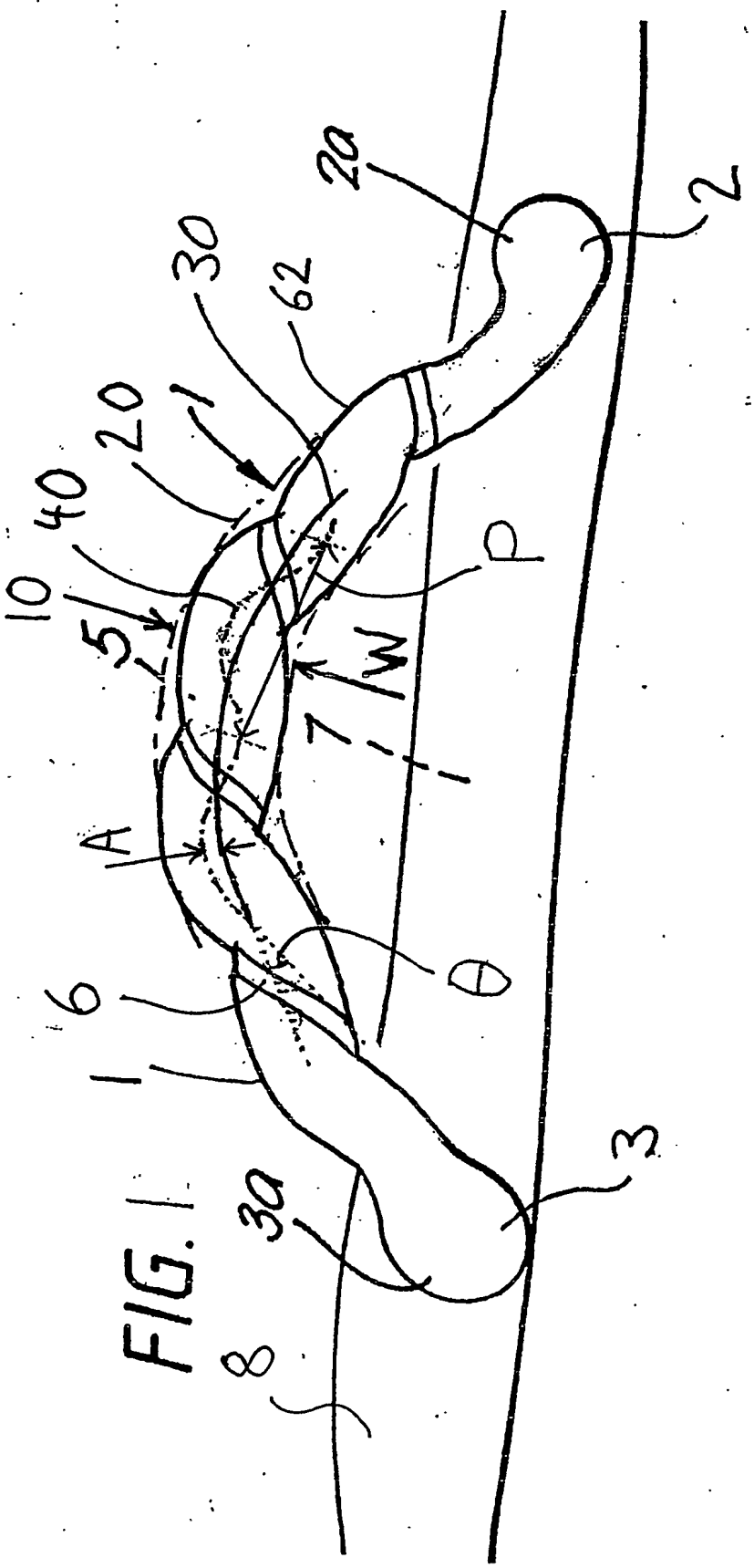

FIG. 1

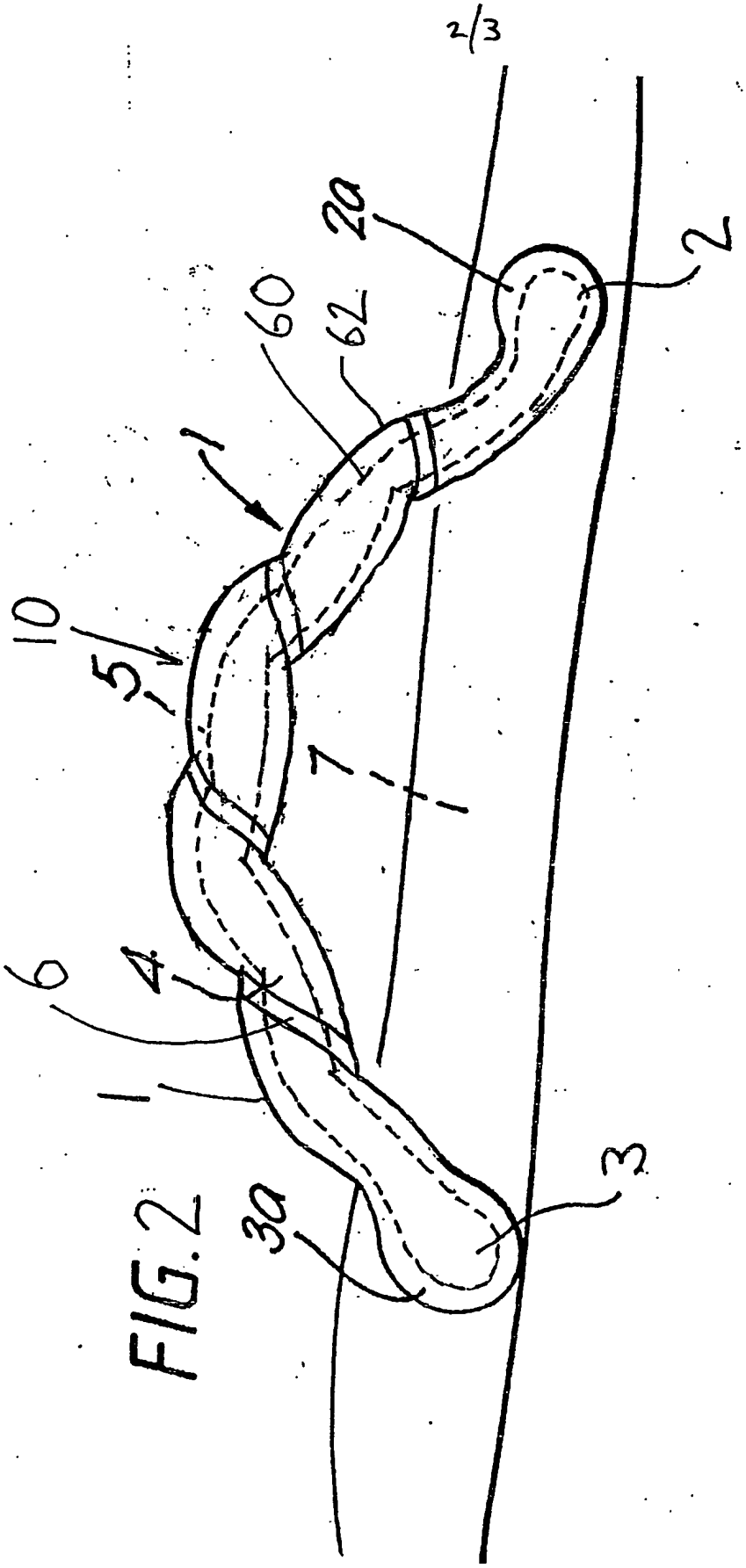

FIG. 2

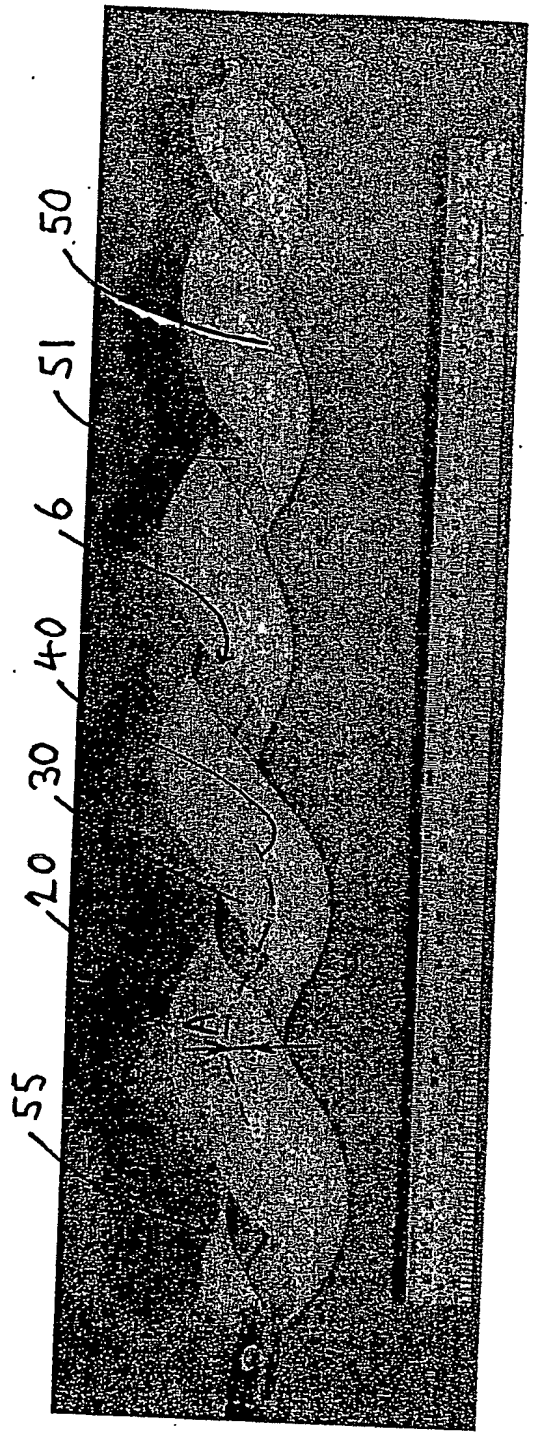

Fig.3

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Tubing

This invention relates to artificial, or modified natural, tubing for body fluid flow and to tubing in other biomedical applications.

We have previously proposed that the flow pattern in arteries including the swirling pattern induced by their non-planar geometry operates to inhibit the development of vascular diseases such as thrombosis, atherosclerosis and intimal hyperplasia.

It is known from WO 95/09585 to provide a vascular prosthesis comprising a length of generally hollow tubing having openings at both ends thereof and including a non-planar curved portion so as to induce swirl flow in blood flowing through the curved portion. As explained in that publication, the swirl flow induced by skewing of the blood flow within the non-planar curved portion improves flow characteristics and reduces the potential for deposit build-up and vascular disease including intimal hyperplasia.

In WO 98/53764, there is disclosed a stent for supporting part of a blood vessel. The stent includes a supporting portion around which or within which part of a blood vessel intended for grafting can be placed so that the stent internally or externally supports that part. The supporting portion of the stent is shaped so that flow between graft and host vessel is caused to follow a non-planar curve. This generates a swirl flow, again to provide a favourable blood flow velocity pattern which reduces the occurrence of vascular disease, particularly intimal hyperplasia.

In WO 00/32241, there is disclosed another type of stent, in this case including a supporting portion around which or within which part of an intact blood vessel other than a graft can be placed. This supporting portion can prevent failure of the vessel

through blockage, kinking or collapse. Again, the supporting portion of the stent is of a shape and/or orientation whereby flow within the vessel is caused to follow a non-planar curve. Favourable blood flow velocity patterns can be achieved through generation therein of swirl flow within and beyond the stent. Failures in blood vessels through diseases such as thrombosis, atherosclerosis, intimal hyperplasia can be significantly reduced.

Further aspects of how swirl flow is beneficial are explained in the above publications. It is further explained in Caro et al. (1998) J. Physiol. 513P,2P how non-planar geometry of tubing inhibits flow instability.

It has been proposed in WO 00/38591 to use internal helical grooving or ridging to induce helical flow. However, the use of ribs or grooves in an otherwise cylindrical tube may not reliably induce swirl flow across the entire cross-section of flow. There may be a tendency for the flow nearer to the centre of the tube to follow a linear path, particularly for flows at higher Reynolds numbers. Furthermore, the ratio of the wetted perimeter to the cross-sectional area of a tube is increased by the provision of ridges or grooves. This may lead to increased flow resistance and a consequent pressure loss, and damage to blood vessels and blood cells and the development of pathology.

It is also proposed in WO 00/38591 to use a non-circular cross-section tube which is twisted. In these proposals, the centre line of the tube follows a straight path, i.e. the centroids of adjacent cross-sectional slices through the tube define a straight locus or centre line. Again, therefore, there may be a tendency for the flow nearer to the centre of the tube to follow a linear path.

A further proposal in WO 00/38591 is to provide a circular-section tube bent into a cork screw shape.

In WO 02/098325 there are various proposals for

cylindrical external structures for placement outside of blood flow conduits in order to influence the internal geometry of the conduit lumen. By providing ribs or other radially inwardly projecting helical members, the cross-sectional shape of the lumen is modified from the outside of the conduit. Some of these structures, such as those shown in Figures 1 to 4 and 6 to 10, have a non-circular cross-sectional shape which twists along the length of the structure, so as to have a straight centre line. It is necessary for such structures to be relatively tight-fitting on the blood flow conduit, in order to impose the required internal geometry on the conduit. The proposal of Figure 5 has a circular cross-sectional shape and is coiled in the manner of a cork screw.

It is known to use flexible synthetic materials such as polyester to manufacture an external stent or sheath for use in an arteriovenous bypass grafting procedure. Such sheaths are generally of cylindrical shape. A known cylindrical sheath is disclosed in GB 2298577, comprising a 6 mm diameter polyester lock-knit tube externally supported with helically wound (with a very large helix angle, close to 90°) polypropylene.

If tubing is made from flexible material, such as synthetic fabric, but rather than being formed as a cylinder is instead formed so that its centre line follows a substantially helical path, it is easily capable of "straightening out", involving a reduction in the amplitude of the helix and a corresponding increase in the pitch of the helix and in the length of the tubing (i.e. axial extension). The benefits of swirl flow discussed above may then be reduced or lost.

According to one aspect of the invention there is provided artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, comprising a wall defining a longitudinally extending cavity having a centre line

following a substantially helical path, and the wall having a helical portion extending longitudinally and circumferentially so as to resist reduction of the amplitude of the helical centre line.

A helical portion according to the invention can therefore help to maintain the desired amplitude of the helical centre line, and hence maintain the desired swirl fluid flow characteristics.

There are a number of situations where tubing could be subjected to "straightening out" effects tending to cause helical amplitude reduction. These include internal pressurisation by a fluid or by pressurisation of a flexible conduit within the tubing, for example in response to arterial pressure, or axial extension if the tubing is used in the vicinity of a joint, or a combination of the two. Although there may still be a reduction in amplitude when the tubing is subjected to such straightening out forces, the amount of this reduction is less than would be the case without the helical portion.

In general, the helical portion will have a lower extensibility as compared to adjacent portions of the tubing. It will normally have the same pitch as the helical centre line of the tubing wall so as to conform therewith.

Certain preferred embodiments are concerned with artificial or modified natural tubing of the human or animal body, more particularly artificial or modified natural tubing for blood flow. The invention is particularly suitable for *in vivo* tubing, such as vascular prostheses and stents or sheaths external to intact blood vessels or blood vessels intended for grafting. It is also suitable for vascular access grafts.

In certain cases, the longitudinal cavity of the tubing wall itself provides the lumen for body fluid flow. The fluid may then act directly on the tubing

wall and create the internal pressurisation tending to straighten out (i.e. to increase the pitch and reduce the helical amplitude) the tubing and hence the lumen. This is resisted by the helical portion.

In other cases, the tubing acts as an external sheath to maintain helical geometry in a flexible conduit, which may itself be artificial but is preferably a natural vessel, more preferably an intact blood vessel or a blood vessel intended for grafting. The fluid then pressurises the contained flexible conduit which in turn acts on the tubing, again tending to straighten out the tubing and reduce its helical amplitude. This tendency is resisted by the helical portion, thereby helping to maintain the helical geometry of the lumen of the flexible conduit.

The external sheath preferably fits loosely round the flexible conduit, so that the flexible conduit is not significantly restricted when expanding under internal pressurisation. The helical geometry may be imposed on the flexible conduit by the tubing without requiring a tight fit, providing the amplitude of the tubing helical centre line is sufficiently large. This is in contrast to the proposals discussed above having helical ribs or twisted non-circular cross-sections, in which a tight fit is needed in order to impose their geometry on the wall of the contained conduit. A loose fit, as preferred in the present invention, may be beneficial in preventing the development of intimal hyperplasia, as discussed by V. Vijayan et al., in Eur J Vasc Endovasc Surg 24, 13-22 (2002). A loose fit may involve the inner diameter of the external sheath being a few millimetres larger than the diameter of the expanded fluid conduit, preferably about 3-6 mm larger.

The helical portion may be thicker in the radial direction than adjacent portions of the tubing wall. This is a way of achieving the result of the helical portion having lower extensibility than the adjacent

portions. Alternatively or additionally, the helical portion may be made from a material different from that of adjacent portions of the tubing wall.

In this specification, the amplitude of the helical centre line refers to the extent of displacement from a mean position to a lateral extreme. So, the amplitude is one half of the full lateral width of the helical centre line.

In order to avoid excessive lateral bulk, the amplitude of the helical centre line of the tubing longitudinal cavity, once internally pressurised, may be less than or equal to one half of the internal diameter of the tubing. There is then a "line of sight" along the inside of the tubing, unlike in the case of a corkscrew configuration where in effect the helix is wound around a core (either solid, or "virtual" with a core of air). We have found that the flow at the line of sight generally has a swirl component, particularly for higher Reynolds numbers, even though it could potentially follow a straight path.

For the purposes of this specification, the term "relative amplitude" of a helical tubing is regarded as the amplitude of the helical centre line divided by the internal diameter. So, in the tubing in which the amplitude of the helical centre line is less than or equal to one half of the internal diameter of the tubing, this means that the relative amplitude is less than or equal to 0.5. Relative amplitudes less than or equal to 0.45, 0.40, 0.35, 0.30, 0.25, 0.20, 0.15, 0.10 or 0.05 may be preferred. It is however preferred for the relative amplitude to be at least 0.05, more preferably 0.10. This can help to ensure that the desired swirl flow is induced. It is expected that any straightening out of the tubing, and hence reduction in the relative amplitude, when the tubing is in use will not be significant, because of the presence of the helical portion.

The angle of the helix is also a relevant factor in balancing the space constraints on the tubing with the desirability of maximising the cross-sectional area available for flow. The helix angle is preferably less than or equal to 65°, more preferably less than or equal to 55°, 45°, 35°, 25°, 20°, 15°, 10° or 5°. As with relative amplitudes, the helix angle may be optimized according to the conditions: viscosity, density and velocity of fluid.

Generally speaking, for higher Reynolds numbers the helix angle may be smaller whilst satisfactory swirl flow is achieved, whilst with lower Reynolds numbers a higher helix angle will be required to produce satisfactory swirl. The use of higher helix angles will generally be undesirable, as there may be near wall pockets of stagnant fluid. Therefore, for a given Reynolds number (or range of Reynolds numbers), the helix angle will preferably be chosen to be as low as possible to produce satisfactory swirl. Lower helix angles result in smaller increases in length as compared to that of the equivalent cylindrical tubing. In certain embodiments, the helix angle is less than 20°.

It will be appreciated that in pulsatile flow, the Reynolds number will vary over a range. Typical mean resting arterial blood flow Reynolds numbers are about 100, reaching peak values of two or three times that in pulsatile flow and three to four times the mean during exertion. Therefore the extent to which swirl flow is promoted will vary likewise. Even if there are stagnant flow regions at lower Reynolds numbers, because for example a low helix angle and/or a low relative amplitude has been selected, these will tend to be flushed out during periods of flow when the Reynolds numbers are higher.

The tubing may be made with substantially the same relative amplitude and helix angle along its length. There may be small variations when the tubing is in use,

caused by elongation or contraction of the tubing portion due to tensile loading or caused by torsional loading. However, there may be circumstances in which the tubing portion has a variable helix angle and/or relative amplitude, either to suit the space constraints or to optimise the flow conditions.

For reasons of manufacturing simplicity, it may be preferred for the tubing to have a substantially constant cross-sectional area along its length. Again, there may be variations in use caused by loading on the tubing.

The tubing with the helical centre line may form just part of the overall length of a longer piece of tubing or the helical centre line may continue for the entire length of the tubing. For example, an external sheath or prosthesis may have tubing with the geometry of the invention over part of its length or over substantially its entire length.

The helical tubing may undergo a fraction of one complete turn, for example one quarter, one half or three quarters of a turn. Alternatively, the helical tubing undergoes at least one turn, more preferably at least a plurality of turns. Repeated turns of the helix along the tubing will tend to ensure that the swirl flow is maintained.

The tubing may extend generally linearly. In other words, the axis about which the centre line of the tubing portion follows a substantially helical path, may be straight. Alternatively the axis may itself be curved, whereby the envelope occupied by the tubing is curved, for example to produce an "arch" shaped tubing. The bend of the arch may be planar or non-planar, but should be such that swirl is maintained and certainly not cancelled by the geometry of the bend. Thus, for example, a prosthesis or stent may be generally "arch" shaped (planar or non-planar).

It may be desired to split the tubing axially, for

example when it is applied to an intact blood vessel or a blood vessel being used in a bypass graft procedure, enabling the vessel to be inserted sideways through the split rather than being fed longitudinally from one end to the other. The tubing could then be reconstituted with the conduit (i.e. vessel) contained within it by some fastening procedure, or for example by means of surgical sutures.

The tubing geometry disclosed herein may be used as in various biomedical applications e.g. in various arteries (such as in the coronary and renal arteries), in veins, and in non-cardiovascular applications such as in the gastro-intestinal (e.g. bile or pancreatic ducts), genito-urinary (e.g. ureter or urethra) or the respiratory system (lung airways). Thus, the invention extends to tubing for body fluids other than blood.

Moreover, the tubing may be used in equipment for conveying body fluid. Examples are cardiopulmonary bypass equipment, kidney haemodialysis equipment and blood administration or withdrawal equipment.

The invention also extends to methods of manufacturing tubing.

According to another aspect of the invention, therefore, there is provided a method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising positioning a generally tubular, flexible wall adjacent to a further flexible member, twisting the tubular flexible wall and the flexible member around each other, and causing the tubular flexible wall to retain, at least partly, the twisted shape.

The further flexible member may for example be another generally tubular, flexible wall. The step of at least partially retaining the twisted shape may be that of allowing a thermoset tubing to cool.

In view of the potential straightening out effects

on tubing having a twisted shape when the tubing is in use, as discussed above, it is preferred to provide the tubing flexible wall with a helical portion extending longitudinally and circumferentially and for assisting in retaining the twisted shape. In order that the helical portion will complement the twisted shape achieved by the twisting step, it is preferably positioned to lie adjacent to the flexible member (for example in contact therewith).

According to a further aspect of the invention, there is provided a method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising arranging an elongate member helically along a generally tubular, flexible wall so that the elongate member extends longitudinally and circumferentially of the tubular wall, tensioning the elongate member to cause the wall to define a longitudinally extending cavity having a centre line following a substantially helical path, and causing the wall to retain, at least partly, the shape with the longitudinally extending helical cavity.

The helically arranged elongate member thus serves to deform the tubular wall to the shape with the longitudinally extending helical cavity. It may also form the helical portion of the tubing for resisting reduction of the amplitude of the helical centre line, i.e. to help it retain its shape. The elongate member may advantageously therefore serve a dual function and simplify manufacture.

It will generally be undesirable for the cross-sectional shape of the tube to be distorted, for example flattened, during tensioning. Preferably, therefore, the tubular wall is reinforced to assist it in maintaining its cross-sectional shape during tensioning of the elongate member. The reinforcement may be integral with or adherent to the tubular wall, for

example comprising a helical winding with a large helix angle, as is known for example from GB 2298577. Alternatively, or additionally, it may be desirable to provide reinforcement in the form of internal support for the tubular wall during tensioning of the elongate member. A flexible rod or tube or a spring may be inserted into the tubular wall to provide internal support and removed after the desired geometry has been at least partly retained.

A preferred cross-sectional shape of the longitudinally extending helical cavity is substantially circular. If reinforcement is provided, it may then help the tubular wall to keep to this shape.

The step of at least partially retaining the tubular wall in a shape with a longitudinally extending helical cavity is preferably a thermosetting step. Preferably therefore the materials of the tubular wall and the elongate member are such as to permit thermosetting of the tube in the desired shape. It is preferred for the elongate member to be such that it retains its tension when heated, i.e. it does not soften or melt to the extent that it allows the tubular wall to straighten out. The elongate member preferably also bonds to the tubular wall when heated, for example by melting. Then, when cooling takes place the elongate member is bonded to the tubular wall and holds it in the shape with the longitudinally extending helical cavity. An elongate member made of a biocompatible polymer, e.g. polypropylene, heated to just above its melting point for an appropriate time can provide both the tension retention and the bonding properties.

Alternatively, the elongate member may be of composite construction, including a first material which retains tension when heated and a second material which bonds to the tubular wall. The elongate member may then comprise a tensile element, such as a metal wire, in a sleeve for bonding to the tubular wall. The sleeve may

be made of a biocompatible polymer which can soften sufficiently when heated to bond to the tubular wall. The tensile element may if desired be removed from the sleeve after the tubular wall has set in the desired shape. This may be of benefit if the tensile element is not biocompatible.

According to another aspect of the invention, there is provided a method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising providing a generally tubular wall with a helical portion extending longitudinally and circumferentially, the helical portion being less extensible than adjacent portions of the wall, and radially expanding the wall, whereby the helical portion causes the wall to define a longitudinally extending cavity having a centre line following a substantially helical path.

It is preferred in the above method to cause the tubular wall to retain, at least partly, the shape with the longitudinally extending helical cavity. This may be achieved for example by thermosetting.

Certain preferred embodiments of the invention will now be described by way of example and with reference to the accompanying drawings, in which:

Figure 1 is a perspective view of a vascular graft, with the grafted vessel omitted for clarity;

Figure 2 is a view similar to that of Figure 1, showing the grafted vessel; and

Figure 3 is a view of an experimental balloon.

The vascular graft 10 shown in Figures 1 and 2 comprises tubing 1 forming an external sheath to a grafted vessel 60 and having a substantially circular cross-section. The tubing is coiled into a helix of constant amplitude A (as measured from mean to extreme), constant pitch P, constant helix angle θ and a swept width W. The tubing 1 is contained in an imaginary

envelope 20 which extends longitudinally and has a width equal to the swept width W of the helix. The envelope 20 may be regarded as having a central longitudinal axis 30, which may also be referred to as an axis of helical rotation. The illustrated tubing 1 has a curved axis 30. The tubing has a centre line 40 which follows a helical path about the central longitudinal axis 30.

The tubing 1 has a helical portion 6 extending longitudinally and circumferentially with the same pitch as pitch P of the helical centre line 40. The helical portion 6 consists of a strip of material secured to the wall 62 of the tubing 1.

The tubing 1 has an inlet 2 at one end and an outlet 3 at the other end. The tubing has inlet 2a and outlet 3a flaps at its ends which have been surgically fastened by suturing to regions of an artery 8 remote from a blockage 7 in the artery, the graft 10 thus acting as an arterial bypass graft. It could also be surgically connected between an artery and a vein so as to serve as a vascular access graft for e.g. renal dialysis.

Figure 2 shows the grafted vessel 60 contained in the tubing 1, the tubing acting as an external sheath. The vessel 60 is a loose fit in the tubing, even when pressurised, but nevertheless has a tendency to try and straighten out the helical geometry of the tubing 1. This is resisted by the helical portion 6, by virtue of its relatively lower extensibility as compared to the rest of the wall 62 of the tubing.

Blood from the circulatory system can flow from the inlet 2 to the outlet 3 along a hollow interior or lumen 4 of the vessel 60. The non-planar curvature of the vessel, as supported by the tubing 1, induces a swirl to the flow to improve circulation and resist the formation of potentially damaging deposit build up and pathology within the interior. The swirl flow may also resist the build up of hyperplasia at the join and downstream of

the join with the vein or artery.

It will be seen that the prosthesis 10 in Figure 3 is generally arch shaped. This arch may itself be provided in a single plane. If the arch is non-planar then this will also tend to induce swirl flow and it will be important to ensure that the swirl flow induced by the non-planar arch is in the same direction as that induced by the helical tubing 1.

The tubing 1 may be made of various materials. Suitable bio-compatible materials are commercially available and known to those skilled in the art. One suitable material, known for use as an external sheath, is polyester. A knitted polyester yarn such as polyethylene terephthalate, known as Dacron (trade mark) is a particular example. The helical portion may be made of the same material or another material, such as polypropylene. The helical portion, rather than being a separate strip secured to the wall 62 of the tubing 1, may be an integral part thereof, for example by being knitted or stitched in to the wall.

Figure 3 shows the result of an experiment carried out on a toy balloon 55. The balloon was of the elongated type. It was supported, without being inflated, on a cylindrical rod and a plastic strip 51 cut from another balloon was glued onto the outside of the supported balloon to form a longitudinally and circumferentially extending helical strip 6. A straight line 50 was drawn along the balloon. After the glue had set, the balloon was inflated and the inflated balloon is shown in Figure 3.

It will be seen that the inflated balloon 55 has a helical lumen. As with the tubing for fluid flow, it has a helical centre line 40, which follows a helical path about a longitudinal axis 30. The longitudinal axis is at the centre of an imaginary cylindrical envelope 20 within which the balloon is contained. The amplitude A of the helix is shown in Figure 3.

It will be noted that after inflation the straight line 50 adopts a wave shape which remains consistently along the same side of the balloon, so that the entire line 50 remains visible in the elevation view of Figure 3.

The balloon of Figure 3 starts as a cylindrical membrane with a helical portion which is of greater (in this case double) wall thickness than the rest of the balloon. During inflation the thicker helical portion will tend to resist extension in all directions, including circumferential and longitudinal directions, thereby influencing the shape of the expanded balloon. Instead of adopting the normal cylindrical shape, the balloon forms a shape with a helical centre line 40.

The balloon is internally pressurised in a manner to some extent analogous with the internal pressurisation of the tubing of the preferred embodiments of the invention. The helical portion causes what would otherwise be a cylindrical shape to adopt and maintain helical geometry. A similar effect is obtained by the helical portion of the tubing for body fluid flow, wherein the helical portion tends to help the tubing maintain its helical longitudinal cavity, i.e. to resist "straightening out".

A tubing having a wall defining a longitudinally extending cavity having a centre line following a substantially helical path was manufactured as follows.

A pair of flexible cylindrical tubes made from polyester were internally supported by insertion of respective closely fitting coiled springs. The two supported tubes were then positioned adjacent to each other and twisted around each other. The pair of tubes were thermoset in the twisted configuration by immersion in hot water followed by removal and cooling. The tubes were separated and the coil springs removed. The internal geometry of each tube so formed consisted of a longitudinally extending cavity having a centre line

following a substantially helical path. One of the tubes was subjected to internal pressurisation by insertion of a cylindrical balloon which was then gently inflated. Because of the flexible nature of the material forming the tube, the effect of the internal pressurisation was to straighten out the helix, in that the pitch was increased and the amplitude decreased.

Such a straightening out effect is however resisted by the use of a helical portion applied to the tube, as described herein. The helical portion is applied to each of the tubes before they are deformed and thermoset as described above. During the step of twisting the two tubes around each other, they are positioned so that their respective helical portions lie in contact with each other.

In an alternative manufacturing method, only one tube, rather than two, is used. An elongate member, in the form of a thread, is helically wound round an initially cylindrical tube. The thread is tensioned and causes the tube to distort helically, such that its longitudinally extending cavity has a centre line following a substantially helical path. The pitch is dictated by the pitch of the winding of the thread. The amplitude is dictated by the tension on the thread. The tension, and hence the helical deformation, is maintained by securing the ends of the thread, for example to a suitable rig. The deformed tube is then heated so as to thermoset and so as to soften the thread sufficiently for it to bond to the tube. The thread therefore serves the purposes first of creating the helical geometry during the tensioning step, and later of helping to retain that geometry when the tube is used and internally pressurised by e.g. arterial pressure.

In a preferred method a knitted polyester yarn such as polyethylene terephthalate, known as Dacron (trade mark), is a suitable material for the tube, whilst the elongate member may be polypropylene. The tube may be

externally supported with helically wound (with a very large helix angle, close to 90°) polypropylene. With these materials the heating step is carried out by heating the tube and tensioned thread in an oven at 140°C.

In another alternative manufacturing method using only one tube, the tube is initially cylindrical, with a helical portion. It is internally pressurised using an appropriate inflatable device, such as a balloon, before thermosetting. It adopts the helical geometry in the same manner as the balloon shown in Figure 3. The helical portion thus serves the purposes first of creating the helical geometry during the inflation step, and later of helping to retain that geometry when the tube is used and internally pressurised by e.g. arterial pressure.

If the tubing is to have an axial split, e.g. for sideways insertion of a vessel, this may generally follow a wave shaped line such as line 50 of the balloon. A fastening means for the split may therefore be conveniently provided in a manner extending substantially linearly (i.e. substantially straight) on the cylindrical tube before it is deformed to the desired non-cylindrical, helical shape (preferably by one of the methods described above). Such a cylindrical tube may itself be formed from a flat sheet which is rolled up to form the cylinder and the fastening means could then be provided along the edge or elsewhere on the sheet, preferably extending substantially linearly.

Claims

1. Artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, comprising a wall defining a longitudinally extending cavity having a centre line following a substantially helical path, and the wall having a helical portion extending longitudinally and circumferentially so as to resist reduction of the amplitude of the helical centre line.

2. Tubing as claimed in claim 1, wherein the longitudinal cavity of the tubing wall itself provides a lumen for body fluid flow.

3. Tubing as claimed in claim 1, used as an external sheath around a flexible conduit in which body fluid flows.

4. Tubing as claimed in claim 3, wherein the external sheath fits loosely round the flexible conduit.

5. Tubing as claimed in any preceding claim, wherein the helical portion is thicker in the radial direction than adjacent portions of the tubing wall.

6. Tubing as claimed in any preceding claim, wherein the helical portion is made from a material different from that of adjacent portions of the tubing wall.

7. Tubing as claimed in any preceding claim, wherein the amplitude of the helical centre line divided by the internal diameter of the tubing is at least 0.05.

8. Tubing as claimed in any preceding claim, wherein the helix angle of the helix centre line is less than or equal to 20°.

9. A method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising positioning a generally tubular, flexible wall adjacent to a further flexible member, twisting the tubular flexible wall and the flexible member around each other, and causing the tubular flexible wall to retain, at least partly, the twisted shape.

10. A method as claimed in claim 9, further comprising providing the tubular flexible wall with a helical portion extending longitudinally and circumferentially and for assisting in retaining the twisted shape.

11. A method as claimed in claim 10, wherein the helical portion is positioned to lie adjacent to the flexible member.

12. A method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising arranging an elongate member helically along a generally tubular, flexible wall so that the elongate member extends longitudinally and circumferentially of the tubular wall, tensioning the elongate member to cause the wall to define a longitudinally extending cavity having a centre line following a substantially helical path, and causing the wall to retain, at least partly, the shape with the longitudinally extending helical cavity.

13. A method as claimed in claim 11, wherein the tubular wall is reinforced to assist it in maintaining

its cross-sectional shape during tensioning of the elongate member.

14. A method as claimed in claims 11 or 12, comprising thermosetting the tubular wall in the shape with the longitudinally extending helical cavity.

15. A method of making artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, the method comprising providing a generally tubular wall with a helical portion extending longitudinally and circumferentially, the helical portion being less extensible than adjacent portions of the wall, and radially expanding the wall, whereby the helical portion causes the wall to define a longitudinally extending cavity having a centre line following a substantially helical path.

16. A method as claimed in claim 15, further comprising causing the tubular wall to retain, at least partly, the shape with the longitudinally extending helical cavity.

17. Tubing substantially as hereinbefore described with reference to Figures 1 and 2 of the accompanying drawings.

ABSTRACT

Tubing

Artificial, or modified natural, tubing for body fluid flow, or tubing used in equipment for conveying body fluid, comprising a wall defining a longitudinally extending cavity having a centre line following a substantially helical path, and the wall having a helical portion extending longitudinally and circumferentially so as to resist reduction of the amplitude of the helical centre line.

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